

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

REC'D 25 JAN 2005

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|---|--|---|--|
| Applicant's or agent's file reference<br>12315340/GCP/wm  |  | <b>FOR FURTHER ACTION</b>                           | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No.<br><b>PCT/AU2003/001229</b>   | International Filing Date<br>(day/month/year)<br>19 September 2003 | Priority Date (day/month/year)<br>19 September 2002 |  |
| International Patent Classification (IPC) or national classification and IPC<br>Int. Cl. <sup>7</sup> A61F 2/46 |  |   |  |
| Applicant<br>FLINDERS TECHNOLOGIES PTY.LTD et al  |  |   |  |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

|      |                                     |   |
|------|-------------------------------------|---|
| I    | <input checked="" type="checkbox"/> | Basis of the report   |
| II   | <input type="checkbox"/>            | Priority  |
| III  | <input type="checkbox"/>            | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| IV   | <input type="checkbox"/>            | Lack of unity of invention  |
| V    | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI   | <input type="checkbox"/>            | Certain documents cited   |
| VII  | <input type="checkbox"/>            | Certain defects in the international application  |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application   |

|   |  |
|---|--|
| Date of submission of the demand<br>29 March 2004   | Date of completion of the report<br>17 January 2005                                |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br><b>SWAYAM CHINTAMANI</b><br>Telephone No. (02) 6283 2202 |

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |                |     |
|-------------------------------|----------------|-----|
| Novelty (N)                   | Claims 1 to 27 | YES |
|                               | Claims         | NO  |
| Inventive step (IS)           | Claims 1 to 27 | YES |
|                               | Claims         | NO  |
| Industrial applicability (IA) | Claims 1 to 27 | YES |
|                               | Claims         | NO  |

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 WO 1997/027828 (MASINI)
- D2 US 4274163 (MALCOLM et al)
- D3 US 5725596 (BURKE)
- D4 US 6277123 (MARONEY et al)

The present application defines (claim 1) an implant clamp "for clamping an implant having a base to a bone" characterised by an arm pivotally connected to the support member and an actuating member to cause rotation of the arm relative to a support member. The arm exerts a force on the implant that is perpendicular to the base of the implant. Claim 22 defines a method of fixing an implant to a bone using a clamping member that includes an engagement member which exerts a force on the implant "substantially solely in a direction which is perpendicular to said surface of the bone". Claims 25 and 27 define a further implant clamp with the pivoting arm and actuating member of claim 1 and further characterised by mounting pins passing through connecting holes in the support member.

Document D1 discloses a device to maintain the proper positioning of a prosthetic implant. The clamp illustrated in figure 4 includes a cover (406) (equivalent to a support member), screw clamps (see figure 4) for fixing the cover to the bone (equivalent to the "means for coupling the support to the bone"), a clamp (404) rotationally connected to a post on the cover and a collar (422) that grips the bone. The clamp of D1 resists side to side movements of the implant (see figure 11). An actuating member and a force direction as defined by claim 1 is not evident in D1.

D2 provides a clamp (26) that grips the edges of the tibia and immobilises the prosthesis (14) whilst the space within the bone (see figure 1) is filled with medical cement. A pivoting arm and the actuating means are not disclosed by this document.

Document D3 recites a clamp (92) with a ball seated on the implant and a flange (102) and finger grips (105) to allow the surgeon to apply a force to the implant. Although the force applied to the implant may be viewed as substantially perpendicular to the base of the implant, D3 does provide an actuating member, or a pivoting arm

*Continued on supplemental box..*

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 26 is not clear because it is appended to a subsequent claim.

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of V**

Document D4 provides a clamp to position an implant within a bone cavity. Although it discloses a base and a means of securing the base to the bone, it does not suggest a pivoting arm or an actuating member.

None of documents D1 to D4 disclose or suggest the clamps and method defined in the present application. Claims 1 to 27 satisfy Articles 33(2) to 33(4) of the PCT, the noted claims are novel, inventive and have an industrial application.